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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,235	03/17/2004	Elizabeth Dzeng	Stanford S03-060	5638
39843	7590	12/01/2006	EXAMINER	
BELL & ASSOCIATES 416 FUNSTON ST., SUITE 100 SAN FRANCISCO, CA 94118			GIBSON, ROY DEAN	
			ART UNIT:	PAPER NUMBER
			3739	

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/803,235

Applicant(s)

DZENG ET AL.

Examiner

Roy D. Gibson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 and 33-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 13, 14, 16-31 and 33-36 is/are rejected.
- 7) ☒ Claim(s) 11, 12 and 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Entry of Amendment

Applicant's amendment filed on Sep. 14, 2006 is acknowledged. Claim 32 has been canceled by the applicant, thus claims 1-31 and 33-36 are currently pending.

Prior Rejections or Objections

The following comments pertain to the rejections or objections in the most recent Office action mailed on June 16, 2006. Rejections under 35 U.S.C. 102 and 103 with the Lalonde et al. reference are withdrawn, however, new rejections with the Saab reference and with others are presented below. Claim 10 was only objected to in the prior Office action, therefore, this Office action is non-final.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 13-14 and 22-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Saab (5,624,392).

As to claims 1, 2 and 8-9, Saab discloses a heat exchange catheter system for cooling a target organ, the heat exchange catheter system adapted for placement within an anatomical structure of a subject, comprising:

(a) a first elongate tubular body (Figure 3, # 66) having a proximal end and a distal end,

(b) a second elongate tubular body (62) having a proximal end and a distal end,
and

(c) a transducer (ultrasound probe which inherently has a transducer: see col. 12, lines 39-47);

d) a balloon (70) defining a lumen (64) in fluid communication with both the first elongate tubular body and the second elongate tubular body so as to form a continuous fluid pathway with various types of thermal exchange compositions (see col. 9, line 66-col. 10, line 9), and wherein the balloon, when inflated, is adapted to conform in shape and size to the interior of the anatomical structure such that when placed within the anatomical structure and inflated, the outer surface of the balloon is at least partially in contact with the inner surface of the anatomical structure providing a heat exchange surface by which heat is exchanged between the anatomical structure and interior of the balloon, and whereby inherently a target organ adjacent to the anatomical structure is thereby cooled (col. 11, line 62-col. 12, line 67).

As to claims 3, 4 and 8, Saab further discloses a thermal exchange composition within the balloon lumen and wherein the thermal exchange composition flows within the continuous fluid (liquid) pathway formed by the second elongate tubular body, the first elongate tubular body, and the balloon lumen (Figure 3).

Further to claims 5 and 7, the functional language of these claims are directed to intended use only and does not introduce an additional structure that alters the system.

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The system of Saab clearly is capable of being placed within the esophagus, the uterus, etc. as claimed.

As to claim 6, Saab further discloses the heat exchange catheter system wherein the balloon is shaped and sized for placement in the anatomical structure selected from the group consisting of: the venous system.

As to claims 13 and 14, Saab further discloses the heat exchange catheter system of claim 1 further comprising a third elongate tubular body (74) having a proximal end and a distal end, the third elongate tubular body disposed longitudinally within the second elongate tubular body, and wherein the balloon is sealably affixed to the outer surface of the first elongate tubular body and sealably affixed to the outer surface of the third elongate tubular body, and further comprising a guidewire (Figure 1, # 11) disposed within third elongate tubular body (74) (col. 7, line 58-col. 10, line 23).

As to claims 22-29, Saab discloses all elements of these claims as presented above, where the saccular body is the balloon (70) which forms a flexible and elastic reservoir.

Further to claim 30, the disclosure by Saab of water or saline as a fluid for circulation and cooling/heating inherently requires a pump (see col. 9, line 66-col. 10, line 9).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable Saab.

Although Saab fails to disclose the specific cooling rates claimed, the examiner maintains that even the most rapid rate of 2-5 deg./30 minutes can be realized by the catheter system based on typical performance of the disclosed coolants, as are well known in the art of heat exchange catheters. Furthermore, the broad range claimed reveals the lack of criticality of the rate, and one of ordinary skill in the art would be able to determine such rates by routine experimentation.

Claims 1-3, 31 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al. (5,531,776). Ward et al. disclose all elements of claims 1-3 (Figure 4) and the method of its use (Figure 16 and col. 10, line 60-col. 12, line 8, col. 14, line 30-col.15, line 2 and col. 16, lines 18-28). However, Ward et al. fail to specifically disclose a "transducer", which the applicant has defined as a temperature sensor, among other devices, and therefore, the examiner maintains that at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of Ward et al. to include a temperature sensor at the heat exchange region to monitor and even control the temperature of the cooling fluid as is well known in the art.

Further to claims 35-36, the examiner maintains that even the most rapid rate of 2-5 deg./30 minutes can be realized by the catheter system based on typical performance of the disclosed coolants, as are well known in the art of heat exchange

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catheters. Furthermore, the broad range claimed reveals the lack of criticality of the rate, and one of ordinary skill in the art would be able to determine such rates by routine experimentation.

Allowable Subject Matter

Claims 11, 12 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

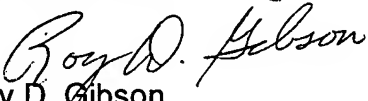
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lafontaine (5,868,735) disclose a cryoplasty device comprising a heat exchange catheter with a balloon and a temperature sensor (22) attached to the balloon.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 571-272-4767. The examiner can normally be reached on Tu-Th, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Roy D. Gibson
Primary Examiner
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November 15, 2006